

REMARKS

Upon entry of the foregoing amendment, claims 1-4 and 7-19 are pending in the application, with claims 1 and 11 being the independent claims. Claims 1 and 11 are sought to be amended. Claims 5 and 6 were cancelled by previous amendment without prejudice to or disclaimer of the subject matter therein. Claims 3, 4, and 18 are currently withdrawn from consideration.

Claims 1 and 11 have been amended to recite that the microcrystalline cellulose has an average particle diameter of 2-10 micrometers. Support for this change can be found in the specification as originally filed, e.g., at page 6, paragraph [0015], lines 1-5. Applicants submit that this change does not raise any new issues of patentability and is being made to put the claims in better form for appeal, as permitted under 37 C.F.R. § 1.116(b)(2).

These changes are believed to introduce no new matter, and their entry is respectfully requested. Reconsideration of this application is also respectfully requested.

I. Rejection of the Claims Under 35 U.S.C. § 103

Claims 1, 2, 7-17 and 19 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 95/34275 in view of JP 0558861. (Office Action, at page 2, lines 7-8.) Applicants respectfully traverse this rejection.

Specifically, the Examiner indicates that he does not believe that the data presented in the Nakao Declaration show unexpected results in light of JP 055861, which the Examiner believes already acknowledges that smaller particle size increases shape-holding ability, so that particle sizes of <10 microns are expected to show enhanced smoothness, shape holding ability, and dispersibility. (Office Action, at page 2, line 16, to page 3, line 2.)

In response to Applicants' argument that powdered and microcrystalline types of particulate cellulose have entirely different physical properties, the Examiner states that this argument is not persuasive because WO 95/34275 (the primary reference) "clearly gives the skilled artisan the option to choose the microcrystalline type over the powdered type if he or she so desires." (Office Action, at page 3, lines 3-8.) Lastly, in response to Applicants' argument that WO 95/34275 teaches away from the claimed invention, the Examiner states that "a reference is good for all of its teachings - not just those embodiments that are preferred by an inventor." (Office Action, at page 3, lines 9-12.)

Applicants continue to maintain their position that the present invention is a classic unobvious selection of particular materials resulting in a combination that exhibits unexpected results. Furthermore, as emphasized in the Amendment and Response Under 37 C.F.R. § 1.111 filed on June 9, 2008, one of skill in the art would have had no reason to arrive at Applicants' oral composition comprising the combination of microcrystalline cellulose having an average particle diameter of 2-10 micrometers with a surface active agent selected from the group consisting of alkyl glucoside and betaine based on WO 95/34275 and JP 0558861.

The cellulose contained in Applicants' claimed oral compositions is microcrystalline cellulose having a relatively low range of average particle diameter of 2-10 micrometers.

As previously noted, WO 95/34275 discloses an oral care composition comprising a particulate cellulose cleaning/polishing agent that "may comprise the powdered and/or microcrystalline type," but that is more suitably highly purified powdered cellulose. Example 6 discloses a toothpaste composition comprising the cellulose abrasive Elcema (powdered cellulose) and cocamidopropyl betaine. Although WO 95/34275 discloses cellulose having a particle size of from about 1 μm to 350 μm (WO 95/34275, at page 4, second paragraph), the most suitable range is disclosed to be "from about 10 μm to about 100 μm , more suitably from about 20 μm to about 70 μm ." See WO 95/34275, at page 4, line 8. Applicants also emphasize again that microcrystalline cellulose and powdered cellulose are compounds having entirely different physical properties. In fact, WO 95/34275 also distinguishes microcrystalline cellulose from powdered cellulose. See WO 95/34275, at page 2, lines 13-25. WO 95/34275 thus appears to teach away from using microcrystalline cellulose having a low range of 2-10 micrometers in oral compositions.

Regardless of the teachings of WO 95/34275 and JP 0558861, however, Applicants continue to submit that the claimed oral compositions do exhibit unexpected effects from incorporation of microcrystalline cellulose with a specific average particle diameter and a specific surface active agent into the composition, as evidenced by the Nakao Declaration submitted with Applicants' response on June 9, 2008, which indicates that a significant effect is exhibited by combining microcrystalline cellulose having an average particle diameter of equal to or smaller than 10 micrometers with the surface active agents alkyl glucoside or betaine. As demonstrated in Nakao's declaration, the excellent effect of the present oral

composition can be exhibited only by a combination of microcrystalline cellulose having a specific average particle diameter of equal to or smaller than 10 micrometers with these specific surface active agents.

The basis of the present invention is that an oral composition can be obtained which does not cause solid-liquid separation during a long period of time, has excellent shape-holding ability and dispersibility in oral cavities and the like, by combining "a specific surface active agent" and "specific microcrystalline cellulose." The specification discloses that "microcrystalline cellulose having an average particle diameter of 10 micrometer or smaller is more preferable and microcrystalline cellulose having an average particle diameter of 2-6 micrometer is most preferable" (see, original specification, paragraph [0015]).

As shown in the experimental results presented in the present specification, it has been confirmed that excellent stability with time is achieved by a combination of a specific surface active agent and microcrystalline cellulose having an average particle diameter of 4 μm (see the specification as originally filed, Table 1, Examples 1 and 4), but is not exerted by a combination of other surface active agents or cellulosic materials (see Comparative Examples 1-4). Moreover, it is shown that the above effects of the present invention are successfully achieved with an oral composition comprising microcrystalline cellulose having an average particle diameter of 3.7, 5.8 and with alkyl glucoside or betaine (see Examples 5, 6 and 9-13).

The data presented in the Nakao declaration demonstrates that (a) for shape-holding ability, a significant effect is achieved in formulations comprising microcrystalline cellulose having an average particle diameter smaller than (5 and 9 μm) with alkyl glucoside or betaine; and (b) for dispersibility in oral cavities, a favorable effect is achieved in formulations comprising microcrystalline cellulose having an average particle diameter smaller than 10 μm with alkyl glucoside or betaine, and that this effect becomes high with a decreasing average particle diameter of microcrystalline cellulose.

In general, with respect to the relationship between shape-holding ability and dispersibility in oral cavities, higher shape-holding ability tends to decrease with dispersibility in oral cavities. However, surprisingly and unexpectedly, the present inventors found that both effects can be simultaneously exerted by combining a specific surface active

agent and microcrystalline cellulose. Such a relationship is suitable for an oral composition, a distinct effect in view of conventional common technologies, and it is an special effect which would not have been expected those of ordinary skill in the art.

WO 95/34275 discloses an oral hygiene composition comprising particulate cellulose including microcrystalline-type cellulose having a size of from about 1 to 350 μm , and use of such composition in the treatment and/or prevention of dental caries and/or gingivitis. It also discloses that particulate cellulose may be used to remove stains from the teeth, to reduce and/or prevent the build-up of such stains, and is effective when used as the sole abrasive ingredient.

JP 5058861 discloses a toothpaste composition formulated with an aqueous suspension of pulverized cellulosic material having 0.3-6 μm particle size. The purpose of JP 5058861 is to provide a toothpaste composition causing no drop in viscosity despite a change in temperature or ionic concentrations while maintaining favorable tube extrudability and shape-retaining ability.

The Examiner seems to consider that the present invention is obvious over WO 95/34275 in the light of JP 5058861, since WO 95/34275 discloses an oral hygiene composition comprising microcrystalline cellulose having an overlapped range of particle diameters with that of the present invention, and JP 5058861 discloses a toothpaste composition comprising pulverized cellulosic material similar to the microcrystalline cellulose of the present invention and having *one* effect of the present invention (shape-holding ability). In other words, the Examiner appears to believe that obviousness follows from attending to only one effect of the present invention with one ingredient, shape-holding ability on a tooth brush, with microcrystalline cellulose.

A primary problem solved by the present invention is to provide excellent stability over time (inhibition of solid-liquid separation) together with holding ability and dispersibility in oral cavities (see, for example, the specification as originally filed, paragraph [0011]). That is, the present invention would not have been complete if the claimed preparation was unstable over time, even if it had excellent shape-holding ability and dispersibility in an oral cavity. In fact, such stability is evaluated in the specification (see specification as originally filed, at Table 1).

Neither WO 95/34275 nor JP 5058861 disclose or suggest this effect of stability over

time with dispersibility in oral cavities for the presently claimed combination of specific surface active agents and cellulose of particular particle size.

Furthermore, Applicants note that “polyoxyethylene/polyoxypropylene block copolymer” and ethylene oxide/propylene oxide copolymers” (trade name ‘Pluronic’) are described in the cited references as a surface active agent that may be used in the disclosed preparations (see, e.g., page 3, paragraph [0011] of JP 5058861, and page 8, lines 23-25, of WO 95/34275). Although the descriptions of these surface active are not identical, they refer to identical compounds. In this respect, it is noteworthy that it is demonstrated in the present specification that a stability with time effect of the present invention is not exerted with such compounds, e.g., with the compound ‘Pluronic F88’ (see specification as originally filed, at Table 1, Comparative Example 4).

In view of this, Applicants believe that the present invention as claimed would not have been obvious in light of WO 95/34275 and JP 5058861. That is, since WO 95/34275 and JP 5058861 do not disclose or suggest a primary problem or effect and a specific combination of surface active agents and microcrystalline cellulose of the present invention, and since the specification demonstrates that an effect of the present invention is exerted only by such the specific combination, and, furthermore, since the specification also demonstrates that the primary effect cannot be exerted with the surface active agent disclosed in WO 95/34275 and JP 5058861, the present invention of Claims 1, 2, 7-10 would not have been obvious in view of the combination of WO 95/34275 and JP 5058861.

In addition, Applicants note that the invention as presently claimed relates to an oral composition comprising a cationic antimicrobial agent and microcrystalline cellulose having an average particle diameter of 2-10 micrometers and that this composition provides an enhanced antimicrobial effect (the antimicrobial agent resides on the tooth surface longer), thereby enhancing prevention of oral cavity diseases.

The experimental results presented in the present specification confirm that the significantly enhanced effect is exerted by a combination of the cationic antimicrobial agent and specific microcrystalline cellulose (see the original specification, Table 2, Examples 14, 15, 17 and 18), but is not exerted by a combination with other cellulosic materials (see Comparative Examples 5-8). However, this effect, as well as the combination of the cationic antimicrobial agent and specific cellulose of the present invention is not disclosed or

suggested either in WO 95/34275 or JP 0558861. Thus, the invention of claims 11-17 and 19 would also not have been obvious in view of WO 95/34275 and JP 0558861.

For these reasons, Applicants respectfully submit that in view of WO 95/34275 and JP 0558861, one of ordinary skill in the art would not have expected the properties of the oral composition as currently claimed. Accordingly, the claimed compositions would not have been obvious in light of WO 95/34275 and JP 0558861.

Applicant believes that the rejection of claims 1, 2, 7-17 and 19 under 35 U.S.C. § 103 has been overcome and respectfully requests that the Examiner withdraw this rejection.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request that the Examiner reconsider all rejections and that they be withdrawn. Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

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